

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA**

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UNITED STATES OF AMERICA,	)	
<i>ex rel.</i> JAMES ALLEN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
GUIDANT LLC, formerly doing business as	)	
GUIDANT CORPORATION,	)	
GUIDANT SALES LLC, formerly doing	)	
business as	)	
GUIDANT SALES CORPORATION,	)	
CARDIAC PACEMAKERS, INC., and	)	
BOSTON SCIENTIFIC CORPORATION,	)	
	)	
Defendants.	)	

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**AFFIDAVIT**

Civ. No.: 11-cv-22 (DWF/AJB)

STATE OF NEW YORK	)	
	)	ss.:
COUNTY OF ERIE	)	

**JAMES F. ALLEN**, being duly sworn, deposes and states:

1. I am the Relator in this action. I am submitting this affidavit to clarify my affidavit of December 21, 2011, previously submitted in opposition to the defendants' motion to dismiss my Amended Complaint.

2. At paragraph "49" of my December 21 affidavit, I describe my February 2006 submission of materials regarding failures of the Prizm 1861 2 DR defibrillators to the FDA. It is absolutely accurate that I provided materials regarding this subject to the FDA in February of 2006. However, I do not recall exactly all the materials I provided to the FDA, as I did not keep a copy of those materials. It should be noted in this regard I was not represented by counsel in connection with this submission.

3. After I obtained counsel and filed the original FDA in July of 2008, as described in my affidavit, I realized it might be important to have copies of the materials I submitted to the FDA in February of 2006. Therefore, on October 23, 2009, I wrote to the FDA requesting a copy of these materials. A copy of this letter is attached as Exhibit A. I received a letter, dated January 27, 2010 in response to this request. A copy of that response is attached as Exhibit B.

4. Enclosed with the response was my letter of February 2, 2006 along with a number of other documents. I do recall and recognize the documents which were sent to me by the FDA in response to my request were included in my February, 2006 submission. However, I do not know whether the FDA sent me copies of all the documents that were submitted by me in February, 2006.

5. There is a handwritten notation on some (but not all) of the pages sent to me by FDA indicating there were 27 pages (presumably in the package I submitted, but this is not at all clear). However, I did not receive 27 pages from the FDA with their letter of January 27, 2010, and not all of the pages were hand-numbered. A copy of what I actually received is attached as Exhibit C.

6. It should be noted that Exhibit C of this affidavit is different from Exhibit C of my December 21, 2011 affidavit. After that affidavit was filed by my attorneys, I realized there were pages included in that exhibit which clearly could not have been part of my February, 2006 submission. Consequently, I thought it was important to submit this affidavit in order to provide as much context and clarity as possible. Attached as Exhibit D are copies of the two pages which had been submitted with my December 21 affidavit which likely were not part of my February, 2006 submission to the FDA<sup>1</sup>. I apologize for any confusion.

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<sup>1</sup> Exhibits C and D of this affidavit contain all of the pages in Exhibit C of the December 21, 2011 affidavit.

7. I assume that the FDA has a complete copy of my February, 2006 submission, and that this material will be available in discovery in this FCA. At this point, I have no reliable record of how many pages were submitted. But I can say to the Court all of the pages enclosed with this affidavit as Exhibit C were, in fact, submitted by me to the FDA in February of 2006.

WHEREFORE, I request an Order of the Court denying the defendants' motion to dismiss my FCA.

/s/ James Allen  
**James Allen**

Sworn to before me this  
27th day of December 2011

/s/ James I. Myers  
Notary Public

Qualified in Erie County  
My Commission Expires: 12/31/14